



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,553	07/17/2003	Moshe Ein-Gal	1307EIN-US	9245

7590 03/11/2008
Dekel Patent Ltd.
Beit HaRofim
Room 27
18 Menuha VeNahala Street
Rehovot,
ISRAEL

EXAMINER

LAURITZEN, AMANDA L

ART UNIT	PAPER NUMBER
----------	--------------

3737

MAIL DATE	DELIVERY MODE
-----------	---------------

03/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/620,553	Applicant(s) EIN-GAL, MOSHE	
	Examiner A. LAURITZEN	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

This action is in response to communications filed 17 January 2008 with a concurrent request for continued examination (RCE). New claim 30 recites limitations that are not supported by applicant's disclosure and therefore new grounds of rejection under the first paragraph of 35 U.S.C. 112 for new matter is presented herein.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant has pointed out that it was previously presented that there is no cited criticality in Applicant's disclosure in providing a second membrane. This point was raised in a showing that providing such a membrane is considered obvious within the skill of the art (per Official notice policy) and to assert, alternatively, that providing a membrane to cover a reflector is considered an obvious matter of design choice within the skill of the art, since this optional second reflector solves no stated problem over configurations used in the prior art. Examiner further provided the *rationale* that it is well known in the art to include membrane(s) to shield source devices and their associated reflectors from propagation media (see Response to Arguments section, p. 2 of the final Office action mailed 18 October 2007; also section 2 of the same Office action). This statement is presented simply to provide rationale for establishing grounds of rejection using the standard of obviousness under 35 U.S.C. 103(a) and it is pointed out that it is not a requisite that this rationale be the same as that of Applicant, only that it be a legitimate reasoning as to why membranes would be provided in the claimed configuration within the skill of the art.

Examiner previously cited Oppelt (US 5,279,282) for disclosing a vibratory membrane in a shockwave source device; Hassler (US 5,309,897) discloses a source device with vibratory membrane and propagation medium (abstract) and an associated reflector [21] having a

Art Unit: 3737

membrane [12] that coincides with it (col. 4, lines 31-32; also col. 5, lines 7-10); Grunewald (US 5,174,280) discloses a source surrounded by radiating membrane (col. 3, lines 43-64) and a reflector with a surrounding membrane that “closes the interior of that liquid-filled space and couples the device acoustically to the body of the patient” (col. 5, lines 1-12). These sources were all cited per Official notice policy (presented in the concluding remarks of the non-final action mailed 10 April 2007 and also in the Response to Arguments section of the final Office action mailed 18 October 2007), in establishing that it is well-known to cover source devices and their associated reflectors by a membrane, thereby providing evidence for the claim made by Examiner in the rejection that it is well known in the art to shield source devices and their associated reflectors from the propagation media by providing a membrane.

Since it has been made clear on the record that it is well-known to cover both shockwave source devices and their associated reflectors with membranes for a variety of reasons, as necessitated by the particular therapy method, it is reasonable to conclude that the configuration claimed would have been obvious to one of ordinary skill in the art at the time of invention as a combination of prior art elements to known methods to yield predictable results.

Applicant’s remarks directed to the sources of Fig. 3 are not clear. Examiner has not in fact asserted that “there is more than one source P because the letter P appears twice in the figure” as Applicant alleges, p. 5. Examiner clarifies the position presented in the final Office action: there are two sources, P and E, each of which is broadly regarded as shockwave source device. The membrane (“sealing ring”) of the first device, P, is a membrane through which the second device, E, passes. It is reiterated, source P sealingly passes through the sealing ring(s) of E, as necessitated by their spatial arrangement in Fig. 3, as diagramed below:

Claim 30 specifies that the spherical membrane is convex with respect to said second membrane that covers an end face of the reflector; however, this feature is not clearly recited in Applicant's disclosure, nor is it reasonably inferred from the drawings.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 20-25, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassler et al. (U.S. Patent No. 5,058,569) in view of Grunewald et al. (U.S. Patent No. 5,224,468).

Regarding claims 20-23 and 25, Hassler '569 discloses a shockwave source device comprising a cylindrical acoustic wave transducer sealed within an excitable membrane and having a longitudinal axis of symmetry (col. 4, lines 10-12; see also coil shockwave source 2 and membrane 1 of Fig. 1) with an at least partially parabolic reflector 33 that is disposed symmetrically on both sides of the longitudinal axis with an end face covered by an external membrane (col. 5, lines 19-22; col. 6, lines 55-57 for the "first" external membrane). This first

Art Unit: 3737

external membrane covering an open end of the device is non-parallel (and generally perpendicular) to the longitudinal axis of symmetry of the device, but it is pointed out that since there is no criticality in providing this feature it is considered an obvious matter of design choice within the skill of the art. Hassler further discloses a propagation medium filling the inner volume of the reflector that separates the reflector from the acoustic wave transducer such that the acoustic waves are reflected towards a focus (col. 5, lines 10-12; lines 30-33). An aperture is formed in the reflector that surrounds the first shockwave source device that is located on the longitudinal axis of symmetry and sealed by a sealing ring (see bore 31 and sealing ring 32; also col. 4, lines 63-68 and col. 5, lines 3-4). The membrane surrounding the source device is excited and moved by the excitation device to generate shockwaves (see voltage generator 20 and col. 5, lines 58-65). A second membrane 1 is disclosed at col. 5, lines 19-22 to surround reflector 33.

Hassler '569 does not disclose a second shockwave source device but Grunewald '468 discloses a shockwave generating system with two longitudinally axisymmetric shockwave source devices with the second spherical acoustic wave source disposed in an aperture and adapted to emit acoustic waves to a common focus (see first source device P and second source E of Fig. 3; col. 3, lines 35-40). The spatial adjacency of the sources suggests the second device sealingly passes through the membrane (here, the sealing ring is in fact a membrane) of the first device.

The reflectors described in both Grunewald and Hassler are understood to have “reflective surfaces” associated therewith. In Hassler, for one, it is clear that the reflectors have different shapes but, alternatively, since there is no stated criticality in providing this feature it is considered to be an obvious matter of design choice within the skill of the art.

Regarding claim 24, the second shockwave source device E of Grunewald '468 is disclosed as a spherical acoustic wave transducer in the embodiment of Fig. 3.

Regarding claim 28, the second shockwave source device E of Grunewald '468 is disclosed as a planar acoustic wave transducer with a focusing lens L that is adapted to focus the shockwaves in the embodiment of Fig. 2.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Hassler '569 to incorporate a second shockwave source (either planar or spherical) as taught by Grunewald '468 to superposition shockwaves of differing characteristics, such as energy density or focus size, by operating the first and second sources independently for improved disintegration of a calculus (see Grunewald '468 col. 1, line 58 – col. 2, line 2).

Regarding claim 30, Hassler et al. establishes that it is known in the art to make use of convex membranes, as they are disclosed to surround the spherical source devices and, specifically, “shaped in the form of a portion of a spherical surface” (col. 1, lines 50-54), so providing a convex membrane is obvious as use of the known spherical source device to which the membrane is conformed will necessarily have a convex-shaped surface.

4. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hassler et al. (U.S. Patent No. 5,058,569) in view of Grunewald et al. (U.S. Patent No. 5,224,468) and Reichenberger (U.S. Patent No. 4,976,255). The modified invention of Hassler '569 adheres to the invention substantially as claimed except for the first and second shockwave source devices being arranged with respect to one another to focus on different foci.

Reichenberger '255 discloses a first shockwave source device for generating a first focus and a second shockwave source device (therapeutic ultrasound source) converging at a second focus (col. 2, lines 47-60).

5. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hassler et al. (US 5,058,569) in view of Grunewald et al. (US 5,224,468), as applied to claim 20 above, further in view of Hoff et al. (US 3,942,531).

The device of Hassler et al. as modified by the disclosure of Grunewald et al. includes all features of the invention as substantially claimed, but is not specific to providing “point sources”; however, in the same field of endeavor, Hoff et al. disclose a shockwave lithotriptic device in which point sources are provided (evidenced by Applicant's disclosure), which will give rise to a series of waves (abstract of Hoff et al). The devices of both Hassler and Grunewald et al. additionally provide shockwave generating means that give rise to a sequence of spherical waves within the propagation medium, so since the sources achieve the same function as the point sources claimed they are regarded as functional equivalents for one another.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Zhong et al. (US 5,800,365) is cited to establish that point source electrohydraulic source will give rise to a series of shock wave pulses “in sequence separated by a specified time delay and propagating coaxially along different pathways before converging at a common focal point where the target concretion is located” (col. 6, line 66 – col. 7, line 7; also Fig. 3).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. LAURITZEN whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A. LAURITZEN
Examiner
Art Unit 3737

/A. L./
Examiner, Art Unit 3737

/Brian L Casler/

Supervisory Patent Examiner, Art Unit 3737

Application/Control Number: 10/620,553
Art Unit: 3737

Page 10